

### **REMARKS/ARGUMENTS**

Claims 1-12 and 23-37 have been cancelled, claims 13-14 and 16-18 amended, and claims 39-50 added. Claims 13-22, and 38-50 are presently pending.

### **THE AMENDMENTS**

New claims 39-50 are directed to a method of treating infertility or of improving fertility, which was previously included in claims 13-22.

None of the amendments present new matter. The new claims are supported by the original claims and the specification as filed, for example, at page 6, lines 10-24; and page 8, lines 1-16. And the amendments to the claims were made to correct typographical errors and to separate the methods of treating infertility and improving fertility from the claims directed to treating endometriosis. None of the amendments are intended in any manner to narrow the meaning or scope of any claim terms, for any reason of patentability or otherwise.

### **THE INTERVIEW**

The courtesies extended by Examiner George to Applicants' representative Rodney Fuller during the interview on May 11, 2004 are noted and appreciated. The comments and amendments presented herein are substantially the same as those that were presented and discussed at the interview. As requested during the interview, Applicants have now cancelled the composition claims (1-10, 36 and 37); amended the method claims to clarify that the method of treating infertility or of improving infertility is associated with inhibiting retrograde contractions or improving uterine contractility (see new independent claim 39); and have included in their response the arguments and citations discussed during the

interview supporting the fact that endometriosis is different than dysmenorrhea --the subject matter of the prior art cited by the Examiner.

## **THE REJECTIONS**

### **Rejection of Claims For Nonstatutory Double Patenting**

The rejection of Claims 1-10, 36, and 37 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-6 and 13-15 of U.S. Patent No. 6,126,959 was maintained.

Applicants have now cancelled claims 1-10, 36 and 37 and therefore respectfully request that this rejection be withdrawn. Applicants reserve the right to file one or more continuation applications to pursue any of the cancelled claims without prejudice.

### **Rejection of Claims Under 35 U.S.C. § 112, first paragraph**

Claims 13-22 were rejected for lack of enablement. The Examiner states that while being enabling for the treatment of endometriosis, the claims are not reasonably enabled for a method of treating infertility or improving fertility.

As discussed during the interview, Applicants have amended claims 13-22 to delete the phrase "or infertility or of improving fertility." Claims 13-22 are now directed solely to a method of treating endometriosis. New claims 39-50 have been added and are directed to methods of treating infertility or of improving fertility by inhibiting retrograde contractions or by improving uterine contractility. The new claims also require the amount administered be sufficient to improve uterine contractility or inhibit retrograde contractions.

With the teachings disclosed in the present specification, one skilled in the art would be enabled to practice the invention --a method of treating infertility, or of improving fertility, by inhibiting retrograde contractions or by improving uterine

contractility -- without any undue experimentation. As set forth on page 8, lines 1-18, by inhibiting retrograde contractions, the rapid transport of sperm from the cervical area to the distal end of the tubes where fertilization takes place can be improved. The retrograde transport has actually been visualized using a technique referred to as hysterosalpingoscintigraphy.

In view of the new claims and the teachings of the present specification, Applicants respectfully request that this rejection be withdrawn.

**Rejection of Claims Under 35 U.S.C. § 102(e) - Harrison Evidenced By Peterson**

Claims 1-3 and 6-10 were rejected as anticipated by Harrison U.S. Patent No. 6,197,327 as evidenced by Peterson U.S. Patent No. 6,207,696. Claims 1-3 and 6-10 are cancelled herein. Applicants therefore respectfully request that this rejection be withdrawn.

The Examiner also maintained the previous rejection of claims 13-19 and 22 as being anticipated by Harrison as evidenced by Peterson for the reasons stated in the previous Office Action dated June 18, 2003, on pages 4-5.

Harrison is directed to a device and method for treating dysmenorrhea. In stark contrast, the instant claims are directed to treating endometriosis or infertility, or to improving fertility. As explained in great detail below, Endometriosis and, even more, fertility and infertility, are only peripherally associated with dysmenorrhea, at best.

The Examiner relied on Peterson to teach that "secondary dysmenorrhea is the pain associated with endometriosis." As we explained during the interview and as we will explain below, there is **no** correlation at all between primary dysmenorrhea and endometriosis, and there is **no** absolute or definite correlation between endometriosis and dysmenorrhea. Furthermore, Peterson itself notes that prostaglandins "are at work, for example, in primary dysmenorrhea (frequently given the short-hand abbreviation

"menstrual cramping"), secondary dysmenorrhea, in the pain associated with endometriosis, in pre-term or premature labor, and in other instances of uterine hypercontractility and ischemia." Col. 4, lines 30-35 (emphasis added). Thus, the cited portion of Peterson is not suggesting that dysmenorrhea "is" the pain associated with endometriosis, as suggested in the Office Action. Rather, Peterson merely lists both dysmenorrhea and the pain associated with endometriosis -- not endometriosis itself -- as two separate, distinct conditions associated with prostaglandins.

Thus clarified, the disclosure of Peterson, even together with Harrison, does not establish a direct connection between dysmenorrhea and the pain associated with endometriosis, let alone with endometriosis itself.

As explained during the interview, endometriosis is different than dysmenorrhea. Dysmenorrhea is defined typically as painful menstruation. Dysmenorrhea afflicts about 50% of menstruating women, with primary dysmenorrhea being much more common than secondary dysmenorrhea. See, for example, Taber's Cyclopedic Medical Dictionary (2001) ("Taber's") at pages 650-51 (copy attached). Primary dysmenorrhea usually begins just before or at menarche, and is thought to be associated with uterine ischemia and increased contractility due to increased production of prostaglandins. Id. at 650. There is **no** correlation between primary dysmenorrhea and endometriosis.

Secondary dysmenorrhea is described as potentially associated with many conditions, including not only endometriosis, but also pelvic inflammatory disease, use of an IUD, fertility problems related to imperforate hymen, uterine leiomyomas, adenomyosis, cervical stenosis, ovarian cysts, or pronounced uterine retroflexion and/or retroversion. Id. at 651. Treatment of secondary dysmenorrhea typically consists of administration of

nonsteroidal anti-inflammatory drugs for pain management, and can include medical or surgical management directed to relieve the underlying problem. *Id.*<sup>1</sup>

In contrast, endometriosis is a condition in which **endometrial tissue has developed abnormally, extending outside the uterus**. See, specification at page 1, lines 13-14; Taber's, at pages 702-03 (copy attached). Classic treatments of endometriosis typically attempt to mimic menopause or pregnancy, thereby also blocking ovulation. Specification at page 1, lines 21-27; Taber's, at 702. If necessary, surgery may be used to correct the condition. "The definitive treatment for endometriosis ends a woman's potential for pregnancy by removal of the uterus, tubes, and ovaries." Taber's, at 703.

Thus, Harrison in view of Peterson do not anticipate the instant claims even with regard to endometriosis, let alone infertility or fertility, which are not even mentioned.

In order for a reference to anticipate a claim, the reference must teach every element of the claim. Neither Harrison nor Peterson teach a method of treating endometriosis using a composition comprising a  $\beta$ -adrenergic agonist and a bioadhesive carrier administered locally to the vaginal mucosa.

One skilled in the art would not consider a treatment for dysmenorrhea -- treating pain -- to be an effective treatment for endometriosis -- treating endometrial tissue that has developed abnormally, extending outside the uterus.

In addition, nothing in Harrison or Peterson teaches a method of treating infertility or improving fertility.

For these reasons Applicants respectfully request that this rejection be reconsidered and withdrawn.

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<sup>1</sup> Note that primary dysmenorrhea may be treated with oral contraceptives or nonsteroidal anti-inflammatory drugs. See Taber's at page 651. However, as discussed above, this type of dysmenorrhea is not associated with endometriosis.

**Rejection of Claims Under 35 U.S.C. § 102(e) - Peterson**

The Examiner maintained the previous rejection claims 6 and 7 as anticipated by Peterson U.S. Patent No. 6,207,696. In view of the cancellation of claims 6 and 7, this rejection is now moot. Applicants therefore respectfully request that the rejection be withdrawn accordingly.

**Rejection of Claims Under 35 U.S.C. § 103(a) - Harrison Evidenced By Peterson**

The rejection of claims 4, 5, 20, 21, 36, and 37 for obviousness over Harrison in view of Peterson was maintained for the reasons set forth on pages 6-7 of the June 18, 2003, Office Action.

Applicants respectfully traverse. First, claims 4-5 and 36-37 have been cancelled. Furthermore, Harrison in view of Peterson does not make claims 20-21 obvious. Harrison addresses only the treatment of dysmenorrhea -- primary and secondary. As fully explained above, there is **no correlation** at all between primary dysmenorrhea and endometriosis and **no** absolute or definite correlation between secondary dysmenorrhea and endometriosis. In fact, secondary dysmenorrhea occurs frequently without any association at all with endometriosis. Peterson fails to remedy the deficiencies of Harrison and does not teach or even suggest that endometriosis itself may be treated with  $\beta$ -adrenergic agonists. Furthermore, neither Harrison nor Peterson disclose or suggest fertility may be improved, or that infertility may be treated, with  $\beta$ -adrenergic agonists. One skilled in the art would not be motivated to treat a subject suffering from endometriosis, *e.g.*, primary endometriosis with  $\beta$ -adrenergic agonists. The prior art simply does not teach or suggest that endometriosis could be successfully treated in this manner.

Thus, even the combination of Harrison and Peterson do not render obvious the instant invention with regard to treating endometriosis, infertility, or improving fertility. Therefore, Applicants request that this rejection be reconsidered and withdrawn.

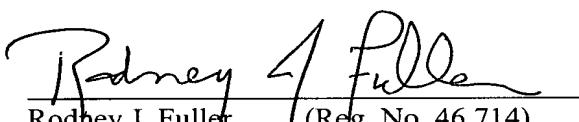
**Conclusion**

In view of the foregoing remarks and amendments it is believed that the entire application is now in condition for allowance. Should any issues remain, please feel free to call Scott Blackman at (202) 371-5795 or Rodney Fuller at (202) 371-5838, to expedite the allowance of all the claims in this application.

No fees are believed due for the claim amendments made herein. Should any fees be required, however, please charge them to Winston & Strawn LLP Deposit Account No. 50-1814.

Respectfully submitted,

Dated: May 26, 2004

  
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PHILADELPHIA

**d. *Intermittens*** Periodic or intermittent inability to execute voluntary limb movements.

**tardive d.** A neurological syndrome marked by slow, rhythmic, automatic stereotyped movements, either generalized or in single muscle groups. These occur as an undesired effect of therapy with certain psychotropic drugs, esp. the phenothiazines.

**traine d.** Pain in the uterus on movement. *Concerning dysmenorrhea.*

**dysphasia** (dis-fa'zé-é) [L. + *phazis*, to talk] Impairment of speech due to a defect of the speech organs.

**dyslexia** (dis-lék'sé-é) [L. + *lexis*, dictation] Difficulty using and interpreting written forms of communication by an individual whose vision and general intelligence are otherwise unimpaired. The condition is usually noticed in schoolchildren by the third grade. They can see and recognize letters but have difficulty spelling and writing words. They have no difficulty recognizing the meaning of objects and pictures and typically have no other learning disorders. SEE: *learning disorder.*

**ETIOLOGY.** Although the exact cause is unknown, evidence suggests that dyslexia may be caused by an inability to break words into sounds and assemble word sounds from written language.

**dyslogia** (dis-lój'é-é) [L. + *logos*, word, reason] Difficulty in expressing ideas.

**dysmnesia** (dis-mé-sé-sis) [L. + *ma-*nesia, insensitivity] Difficulty in masti-

cating.

**dysmaturity** A condition in which newborns weigh less than established normal parameters for the estimated gestational age. SEE: *intrauterine growth restriction.*

**dysmegia** (dis-méj'é-é) [L. + *megos*, big, + *op-*sis, vision] Inability to visualize correctly the size of objects; they appear larger than they really are.

**dysmnesia** (dis-mé-né-é) [L. + *me-*los, limb] Congenital deformity or absence of a portion of one or more limbs.

**dysmenorrhea** (dis-mén-ó-ré-é) [L. + *men*, month, + *horm*, to flow] Pain in association with menstruation. One of the most frequent gynecological disorders, it is classified as primary or secondary. An estimated 50% of menstruating women experience this disorder, and about 10% of these are incapacitated for several days each period. This disorder is the greatest single cause of absence from school and work among menstrual-age women. In the U.S., thus illness causes the loss of an estimated 140,000,000 work hours each year. SEE:

*premenstrual tension syndrome; Nursing Diagnoses Appendix.*

**PATIENT CARE.** Young women experiencing discomfort or pain during menstruation are encouraged to seek medical evaluation to attempt to determine the cause. Support and assistance are offered to help the patient to deal with the problem. Application of mild heat to the abdomen may be helpful. A well-balanced diet, and moderate exercise is encouraged. Noninvasive pain relief measures such as relaxation, distraction, and guided imagery are employed, and the patient is referred for biofeedback training to control pain, and to support and self-help groups.

**congestive d.** A condition caused by excessive fluid in the pelvis. SEE: *pelvic inflammatory disease.*

**inflammatory d.** A condition caused by pelvic inflammation.

**membranous d.** A severe spasmotic dysmenorrhea that is accompanied by the passage of a cast or partial cast of the uterine cavity.

**primary d.** Painful menses. SEE: *menstruation.*

**symptoms.** The pain usually begins just before or at menarche. The pain is spasmotic and located in the lower abdominal cavity, but it may also radiate to the back and thighs. Some individuals also experience nausea, vomiting, diarrhea, low back pain, headache, dizziness, and in severe cases, syncope and collapse. These symptoms may last from a few hours to several days but seldom persist for more than 3 days. They tend to decrease or disappear after the individual has experienced childbirth, the first time, and to decrease with age. Primary dysmenorrhea is much more common than secondary dysmenorrhea.

**ETIOLOGY.** The exact cause is unknown, but uterine ischemia due to increased production of prostaglandins with increased contractility of the muscles of the uterus (i.e., the myometrium) is thought to be the principal mechanism. As in any disease or symptom, the individual's reaction to and tolerance of pain influences the extent of the disturbance experienced. Primary dysmenorrhea is not a behavioral or psychological disorder.

One study revealed that prevalence and severity of dysmenorrhea might have been reduced in those who used oral contraceptives, and that severity was increased in those who had long duration of menstrual flow, who smoked, and who had had early menarche. Exercise did not influence the prevalence or severity of dysmenorrhea.

**DIAGNOSIS.** Cramping, labor-like pains that start just before or at onset

of menstruation are characteristic of dysmenorrhea.

**TREATMENT.** Effective drugs are oral contraceptives and nonsteroidal anti-inflammatory drugs including aspirin. These medicines should be taken in the appropriate dose 3 to 4 times a day and with milk to lessen the chance of gastric irritation.

**secondary d.** Painful menses that manifest some years after menarche. The diagnosis is strongly suggested by a history or finding of use of an intrauterine device; pelvic inflammatory disease; endometriosis; uterine leiomyomas; adenomyosis; fertility problems related to imperforate hymen; cervical stenosis; ovarian cysts; or pronounced uterine retroflexion and/or retroversion.

**TREATMENT.** Nonsteroidal anti-inflammatory drugs are recommended for pain management. Medical or surgical management is directed toward resolving the underlying problem.

**dysmetria** (dis-mé-tré-é) [Gr. *dys*, bad, + *metron*, measure] An inability to control the range of movement (e.g., on trying to touch an object with an index finger).

**dysmetropia** (dis-mé-tro-pé-é) [Gr. *dys*, bad, + *metropia*, vision] Inability to visualize correctly the size and shape of things.

**dysmimia** (dis-mím'e-é) [Gr. *dys*, bad, + *mimia*, imitation] 1. Inability to express oneself by gestures or signs. 2. Inability to initiate.

**dysnesia** (dis-né-zé-é) [Gr. *dys*, bad, + *mneme*, memory] Any impairment of memory.

**dysmorphic** (dis-mórf'ik) Misshapen.

**dysmorphophobia** (dis-mórf-fó-fó-bé-é) [Gr. *dys* + *morphe*, formed, + *phobos*, fear] Substratal fear of being deformed or the illusion that one is deformed.

**dysmotility** (dis-mó-tíl'ë) Any abnormal motility of smooth muscle function in the gastrointestinal tract, such as gastroesophageal, gastric, atony, intestinal pseudo-obstruction, or biliary dyskinesia.

**dysmyotonia** (dis-mí-o-tó-né-é) [Gr. *dys* + *myo*, muscle, + *tonos*, tone] Muscle atony, abnormal muscle function.

**dynaphonia** (dis-ná-fó-né-é) [Gr. *dys*, bad, + *aphasia*, in which the patient forgets words or has difficulty finding words for written or oral expression.

**dysodontosis** (dis-dó-nó-tó-sis) [Gr. *dys* + *odontos*, tooth, + *-tosis*, process] Painful tooth.

**dyspepsia** (dis-pép'sé-é) [Gr. *dys*, bad, + *pepsis*, to digest] Upper abdominal discomfort, often chronic or persistent, colloquially referred to as "indigestion." It is sometimes related to the ingestion of food, and may be a side effect of many medications. It may include such symptoms as fullness, eructation, bloating, nausea, loss of appetite, or upper abdominal pain. SEE: *indigestion.*

**alcoholic d.** Dyspepsia caused by excessive use of alcoholic beverages.

**dysosmia** (dis-óz'mé-é) [Gr. *dys*, bad, + *osme*, smell] Distortion of normal smell perception.

**dystosis** (dis-tóz'sis) [Gr. *dys*, bad, + *osteon*, bone, + *osis*, condition] Defective osification.

**cleidocranial d.** A hereditary disease marked by ocular hypertelorism, exophthalmos, strabismus, widening of the skull, high forehead, beaked nose, and hypoplasia of the maxilla.

**craniocerebral d.** A hereditary disease marked by hypoplasia of the facial bones, downward sloping of the paranasal tissues, defects of the ear, macrostomia, and a fish-faced appearance. It occurs in two forms that are thought to be autosomal dominants.

**mandibulofacial d.** A condition marked by hypoplasia of the facial bones, downward sloping of the paranasal tissues, defects of the ear, macrostomia, and a fish-faced appearance. It occurs in two forms that are thought to be autosomal dominants.

**maxillofacial d.** Hypoplasia of the maxilla and nasal bones resulting in a flattened face, elongated nose, and small maxillary arch with crowding or malocclusion of teeth. SEE: *Bindler's syndrome, maxillofacial syndrome.*

**dysostosis** (dis-óz'sis) [Gr. *dys*, bad, + *osteon*, bone] Impaired pancreatic function.

**dyspareunia** (dis-pá-rú-ne-é) [Gr. *dys* + *paréunein*, to lie beside] Pain in the labia, vagina, or pelvis during or after sexual intercourse.

**ETIOLOGY.** Causes are infections in the reproductive tract, inadequate vaginal lubrication, uterine myomata, endometriosis, atrophy of the vaginal mucosa, psychosomatic disorders, and vaginal foreign bodies.

**TREATMENT.** Specific therapy is given with respect to appropriate vaginal and vulval lubrication. Vaseline is often beneficial.

**dyspepsia** (dis-pép'sé-é) [Gr. *dys*, bad, + *pepsis*, to digest] Upper abdominal discomfort, often chronic or persistent, colloquially referred to as "indigestion." It is sometimes related to the ingestion of food, and may be a side effect of many medications. It may include such symptoms as fullness, eructation, bloating, nausea, loss of appetite, or upper abdominal pain. SEE: *indigestion.*

**dysphagia** (dis-fá-fé-é) [Gr. *dys*, bad, + *phagéin*, to eat] Any disturbance of the act of swallowing.

**dysphoria** (dis-fó-é-é) [Gr. *dys*, bad, + *phórein*, to bear] A state of mental or physical discomfort, distress, or unhappiness.

**dysphoria** (dis-fó-é-é) [Gr. *dys*, bad, + *phórein*, to bear] Any disturbance involving the amount, quality, or timing of sleep. SEE: *sleep.*

**dysphagia** (dis-fá-fé-é) [Gr. *dys*, bad, + *phagéin*, to eat] Defective development of an organism, esp. of an embryo. SEE: *ontogenetic, adj.*

**striae** dyspareunia, sacral backache during menses, and infertility. Dysuria may indicate involvement of the urinary bladder. Cyclic pelvic pain, usually in the lower abdomen, vagina, posterior pelvis, and back, begins 5 to 7 days before menses, reaches peak, and lasts 3 to 4 days. Premenstrual tension and diarrhea may indicate lower bowel involvement. No correlation exists between the degree of pain and the extent of involvement; many patients are asymptomatic.

**DIAGNOSIS:** Although history and findings of physical examination may suggest endometriosis, definitive diagnosis of endometriosis can be established only by direct visualization of ectopic lesions or by biopsy.

**TREATMENT:** Medical and surgical approaches may be used to preserve fertility and to increase the woman's potential for achieving pregnancy. Plan-

macological management includes the use of hormonal agents to induce gonadal atrophy, by maintaining a chronic state of anovulation. Medroxyprogesterone inhibits ovulation and menstruation by inducing pseudomenstruation. Danazol inhibits pituitary gonadotropin release, and Gonadotropin-releasing hormone (GnRH) analogs inhibit release of follicle-stimulating hormone (FSH) and luteinizing

none (LH). Methytestosterone assumes a role in the treatment of endometriosis, although it has not been used to cause endometrial atrophy and provide pain relief; however, gonadal ablation and menstruation are notification.

fected, and pregnancy may occur during therapy.

Surgical management includes laparotomy, lysis of adhesions, and removal of aberrant endometrial cysts and implants to encourage fertility. The definitive treatment for endometriosis ends a woman's potential for pregnancy by removal of the uterus, tubes, and ovaries.

**PATIENT CARE:** Providing emotional support and meeting informational needs are major concerns. The patient is encouraged to verbalize feelings and concerns and to express the effects of the condition on interpersonal relationships. The need for open communication to minimize discomfort and frustration is discussed. The patient is assisted to identify effective coping strategies and to contact, counseling and support, re-

sources.

Diagnostic and treatment options and procedures are explained. Misconceptions are clarified, and understanding and informed consent are validated. The woman is prepared physically and emotionally for any surgical procedure. Procedures include diagnostic laparoscopy and biopsy, laparoscopy with laser vaporization of implants, laparotomy with excision of ovarian masses, or total hysterectomy with bilateral salpingo-oophorectomy. Prescribed pharmacological treatment and analgesics are administered, and the patient is instructed about the desired effects and potential adverse reactions.

Adolescent girls with a narrow vagina and small vaginal meatus are advised to use sanitary napkins rather than tampons to help prevent the risk of toxic shock syndrome.

tion of the uterine cavity. Common offenders include *Staphylococcus aureus*, a normal commensal resident of human skin; *Escherichia coli*, a common inhabitant of the human bowel; *Chlamydia trachomatis*; and *Neisseria*. SEE: pelvic inflammatory disease; toxic shock syndrome

**SYMPOTMS:** The woman usually presents with low, cramping abdominal pain, low back pain, dysmenorrhea, dyspareunia, and fever. Depending on the causative organism, a purulent, mucopurulent, or serosanguinous cervical discharge is seen on vaginal examination. Bimanual palpation finds a tender, boggy uterus. **SEE:** *cervix uteri; endometrium; uterus.*

**DIAGNOSIS:** Culturing the causative organisms establishes the diagnosis.

**TREATMENT:** Antibiotics are chosen to cover aerobic and anaerobic bacteria. **PATIENT CARE:** The patient should be made aware that the infectious process may move (or have moved) beyond the endometrium, involving fallopian tubes, ovaries, pelvic peritoneum, pelvic veins, or pelvic connective tissue. This condition is called pelvic inflammatory disease (PID) and may be acute or subacute. The patient is assessed for changes in the amount, color, odor, and consistency of vaginal discharge. Pain also is assessed for and treated as prescribed. The patient is taught about the drug used for treatment, its desired effect, and any adverse effects. In acute cases, the patient may be febrile; fever is treated with antipyretic drugs if it exceeds 101°F and with PO or intravenous fluids.

IV fluids for hydration, as required. The nurse auscultates for bowel sounds, and if they are absent, the patient is kept NPO. Once culture and sensitivity testing has revealed the bacterial culprit, antibiotic therapy is administered as prescribed, again accompanied by information regarding desired responses and adverse effects. The patient may be placed on bedrest in a semi-Fowler's position to facilitate dependent drainage, so that abscesses will not form, high, in the abdomen. Heat may be applied to the abdomen to improve circulation.

The varied consequences of endometritis are explained. They can include the need for surgery to relieve chronic pain or to manage acute infections that are unresponsive to antibiotic therapy, hidradenitis; tubal scarring; and infertility. The potential or actual loss of reproductive capabilities can devastate the woman's self-concept. All professional providers must assist the patient to defend her self-concept to herself, and

fected, and pregnancy may occur during therapy.

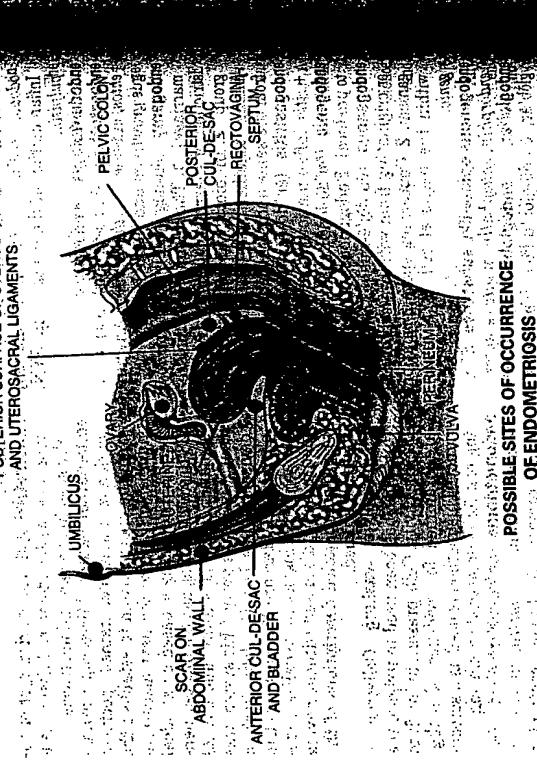
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**SUPERIOR SURFACE OF UTERUS**  
and provide pain  
relief and men-  
strual dys-  
menorrhea.